UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 9, 2002

MEMORANDUM

Subject: Review of Virucidal Data against Foot-and-Mouth Disease Virus for Oxonia Active, EPA Reg. No. 1677-129

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A.I. Chemical Name: Hydrogen Peroxide 27.5%
Peroxyacetic Acid 5.8%

DP Barcode: D284300

Applicant: Ecolab Inc.

MRID# 457124-01

I. BACKGROUND

On May 11, 2001, Ecolab Inc. was granted a conditional registration for the

addition of the Foot-and-Mouth Disease (FMD) Virus to the label of Oxonia Active, EPA Registration No. 1677-129. The conditions for registration included testing of Oxonia Active in an approved facility, testing on two batches of product and total inactivation of the virus or a 3-log reduction if cytotoxcity is present.

II. AGENCY STANDARD FOR LABEL CLAIM

FMD is a virus which causes a serious illness in hoofed animals. It is not considered to be a public health related pathogen, however, the ramifications of this disease being found in animals in the US (specifically cattle and pigs) poses a high economic concern. Historically, the Agency has not required the submission of efficacy data for non-public health related pests. The applicant is required to generate the data, maintain it in their files, and the Agency may call-in that data (when deemed necessary) on a case-by-case basis.

Due to the highly contagious nature of the FMD virus and the extreme economic implications that may arise should the virus be accidentally introduced and spread in the U.S., EPA requires the submission of valid efficacy data (testing and proof that the product effectively controls the virus) prior to approval of a label claim for a product for controlling against the FMD virus.

III. AGENCY STANDARDS FOR VIRUCIDAL TESTING

Test Requirements-Guideline: Subdivision-G 91-2(f) and DIS/TSS-7

The Agency will accept adequate data developed by any virological technique which is recognized as technically sound, and which simulates to the extent possible in the laboratory the conditions under which the product is intended for use. For virucides whose use-directions identify the product as one intended for use upon dry, inanimate, environmental surfaces (such as floors, tables, cleaned and dried medical instruments, etc.), carrier methods, which are modifications of either the AOAC International Use-Dilution Methods (for liquid surface disinfectants) or the AOAC International Germicidal Spray Products as Disinfectants test (for surface spray disinfectants), must be used in the development of the virological data. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus is then assayed by an appropriate virological technique.

Because FMD virus loses viability when dried on carriers, the Agency is accepting data generated by suspension methods.

Performance Standard

The product must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is present, at least a 3-$\log_{10}$ reduction in titer must be demonstrated beyond the cytotoxic level.

IV. SUMMARY OF THE DATA

Testing on Oxonia Active was conducted by the Institute for Animal Health, a Ministry of Agriculture, Fisheries, and Food (MAFF) contract laboratory, using the *Foot-and-Mouth Disease Virus Inactivation Test - MAFF*. This is a suspension method and incorporates the following basic parameters:

Disinfectant product: Oxonia Active Basic and Oxonia Active Alternate at concentrations of 0.2%, 0.4%, and 0.67%.

Virus: Foot-and-mouth disease virus, serotype O_1 British Field Sample 1860 adapted to BHK21. Titer = $10^{6.2}$ - $10^{6.6}$

Cell Line: BHK21 (Baby hamster kidney 21).

Procedure

Aliquots of virus suspension in 1% foetal calf serum were added to appropriate amounts of disinfectant to achieve dilutions of 0.2%, 0.4%, and 0.67% . The mixtures were incubated at 4° C for 10 and 30 minutes. At the end of the 10 and 30 minute contact time, the reaction was stopped by conducting 10-fold dilutions of the mixture into buffer to give a final pH of 7.5. The virus was assayed by plaque technique on BHK21 cells. MAFF requires a 4-log reduction for claims of virus inactivation.

V. RESULTS

Two batches each of Oxonia Active Basic formulation and Oxonia Active Alternate formulation were tested at dilutions of 0.2%, 0.4%, and 0.67% for 10 and 30 minutes. Oxonia Active Basic completely inactivated the foot-and mouth virus in 10 and 30 minutes at dilutions of 0.2%, 0.4%, and 0.67%. Oxonia Active Alternate also achieved complete inactivation of the virus at the same dilutions in 10 and 30 minutes.

VI. CONCLUSIONS

Oxonia Active Basic formulation appears to be virucidal against FMD virus when diluted at 0.2%, 0.4%, and 0.67% at contact times of 10 and 30 minutes. Oxonia Active Alternate formulation appears to be virucidal against FMD virus when diluted at 0.2%, 0.4%, and 0.67% at contact times of 10 and 30 minutes.

VII. RECOMMENDATIONS

The submitted data on Oxonia Active demonstrates the product's ability to inactivate FMDV when tested at a 0.4% (1:256 ppm) dilution for a contact time of 10 minutes at 4° C. The data appears to be sufficient to support full registration for the product Oxonia Active, EPA Reg. No. 1677-129, as a disinfectant against the Foot-and-Mouth Disease (FMD) Virus.

VIII. LABELING

The proposed label for Oxonia Active, submitted April 11, 2001, to add the foot and mouth disease virus under the heading "Virucidal Activity - Poultry and Livestock Pathogens" is acceptable. The label directions state that the surfaces should be saturated with a 0.4% (4 oz. per 8 gallons of water) solution for a period of 10 minutes.